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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,862	08/19/2003	Michael J. Pugia	017191.0036 (MSA-3459)	5515

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Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591

EXAMINER

SOOHOO, TONY GLEN

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,862

Applicant(s)

PUGIA ET AL.

Examiner

Tony G. Soohoo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-43 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-35 and 37-43 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-22-06.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-20 provides for a description of the chambers or passageways having particular geometry, the claims, however, in relation to a "predetermined" volume" during the operation of the method. However the method is imprecise and vague to the breadth and scope of the "predetermined volume". It is unclear what method/process applicant is intending to encompass in the amount of material that is to be dispensed or processed.

3. Claims 25-28, and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25-28 refer to the volume or depth of fluid in comparison within the chamber to that of the containers, however since the volume of the first and second liquid amounts dispensed in operation can not been positively determined (the scope of "predetermined volume" is vague and indefinite), the relative size of the chambers can not be determined since the size is dependent upon an operational characteristic. With regards to claims 29 and 30, the claims point out space in the chamber relative to a flow of fluid during operation of the device and the amount to be provided by the flow. Whereby the flow of fluid is a dependent upon manipulative operation with regards to the amount fed into the chamber, and the claims are directed to an apparatus claim, the space above the level of fluid in the chambers

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during operation of the fluid flow does not provide a positive patentable structural limitation whereby the level of fluid causing the space is directed to a method of operation and not to a structural feature in an apparatus claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

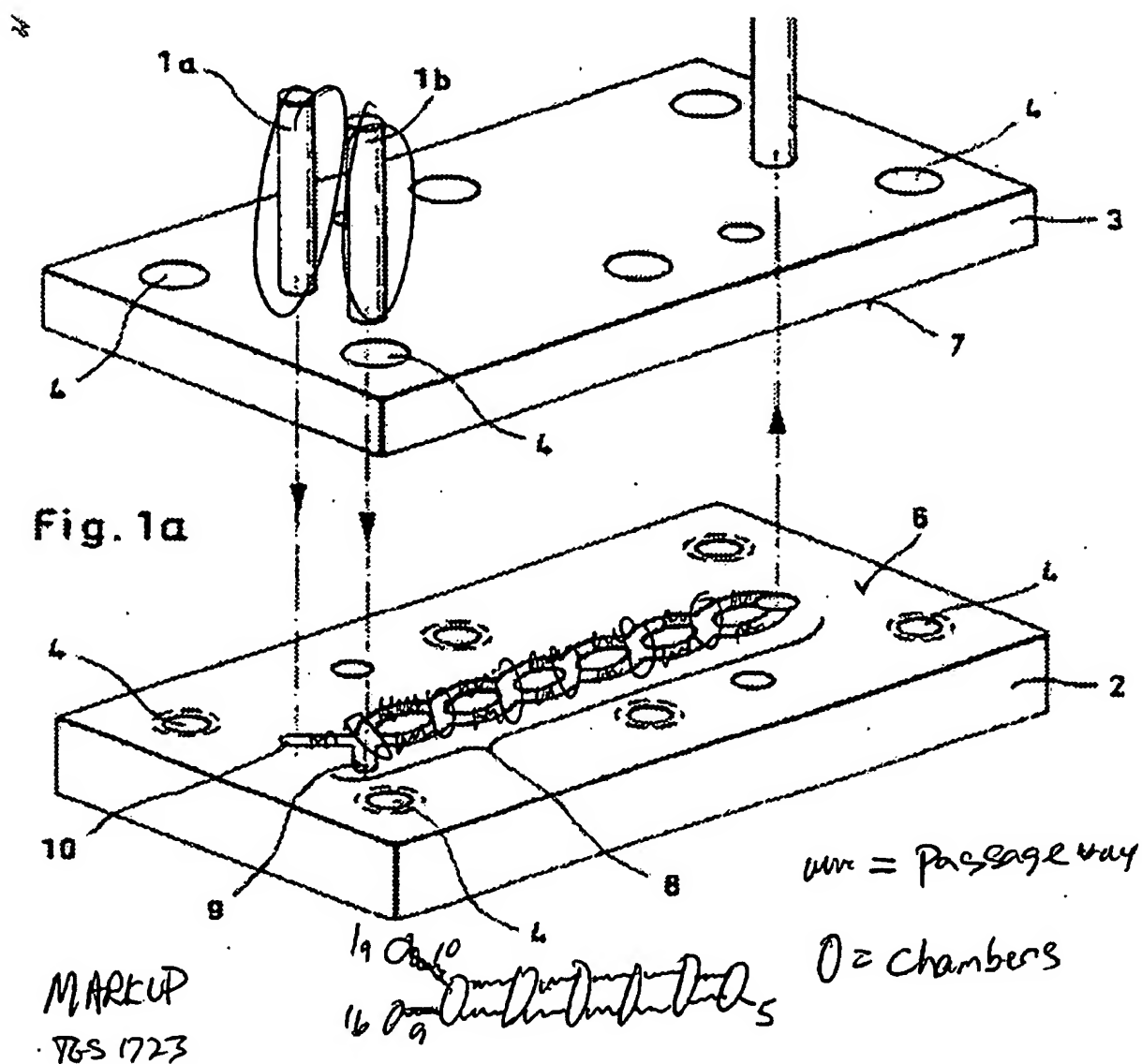
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-2, 4, 20, and 21-22, and 24, are rejected under 35 U.S.C. 102(e) as being anticipated by Koop et al US 6457854 (cited on PTO 1449).

The Koop reference discloses an apparatus and method of use for mixing fluids including two inlets for a 1st and 2nd fluid wells to be fed into a 1st chamber at the intersection of 9,10, a second chamber through seventh at the intersection of the sinusoidal loops which are microchannel capillary passageways along the portion 8, see figure 1, which ends at an outlet chamber at 5 for further processing, whereby each loop side may be deemed as separated passageways. It is noted that one may define any subsequent volume of liquid dispensed from the source wells 1a and 1b as a volume per unit time to be mixed together and one may deem the time unit so small that

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the respective source volumes are only a fraction of the volume in the combined volume in the chamber. It is noted that the claim does not distinguish any batch mode operation such as starting and stopping the flow of fluid from the wells to define a discrete discontinuous volume of separate flow.



Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 6-16, 18-19, 23, 25-35, 38, 40, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koop et al US 6457854.

The Koop (et al) reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of the structure and method of flowing fluid within the chambers having particular volumes, the amount of volume flow level and velocity in the chamber and passageway, the cross sectional dimension, lengths, and number of passageways between channels, and the use of wells as a manner to provide hold the 1st and 2nd liquids.

With regards to having particular volumes, the cross sectional dimension, lengths of the passageways and chambers, a person having ordinary skill in the art in fluid processing would recognize such a size change in geometry would be a direct variable in the production of the amount of fluid which may be processed, and the residence time of processing, accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to modify the volumes, the cross sectional dimension, lengths of the passageways and chambers so as to optimize the amount of fluid processed and the residence time of interaction, since it has been held that discovering an optimum

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value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With regards to the number of passageways between channels, absent any unexpected results with the addition of a 3rd or more channel, it is deemed that it would have been obvious to one of ordinary skill in the art to duplicate at least another channel so that a 3rd sinusoidal pathway is provide to produce additional mixing effect since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

With regards to the amount of level of fluid and velocity of fluid in the method claims, it is commonly known that the level of fluid in a chamber and velocity of fluid flow in a pathway is a direct effective variable in the amount of fluid processed, accordingly absent any unexpected result, it is deemed that it would have been obvious to one of ordinary skill in the art to modify flow velocity and the level of amount of fluid so that the level is of a spacing as recited in the claims so as to optimize the amount fluid that is processed.

With regards to the use of wells, as a manner to hold the 1st and 2nd fluids, the use of wells as a means to hold and supply fluid in microfluidic devices are old and well known, accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to substitute for the feed lines of the Koop (et al) reference with wells so as to better supply a small amount of fluid flow into the mixing device.

With regards to the type of material of the passageways, the use of hydrophilic surfaces in construction of micromixers are old and well known to provide efficient fluid flow, accordingly, it is deemed that it would have been obvious to one of ordinary skill in

the art to substitute for the material of the Koop (et al) reference with passages of hydrophilic surfaces so as to better supply a better flow of fluid.

8. Claims 5, 17, 37, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koop et al US 6457854 as applied to claims 1 and 21 respectively above, and further in view of Nakajima et al 6281254.

The Koop (et al) reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of feeding the fluid in the second chamber in the form of droplets, using ramps or steps to combine the liquids, and structure which prevents premature movement of the fluids.

The Nakajima (et al) reference discloses a mixing channel or chamber 3 having steps or ramp elements 2 which assist in providing a mixing of fluids from the inlet 16 through the inlet chamber 14 to produce droplets at the 2nd side of ramps in the form of droplets, see figure 1, and figure 4, 5, in a controlled movement of the fluids,

In view of the teaching of the Nakajima (et al) reference that additional elements may perfect fluid intermingling, it is deemed that it would have been obvious to one of ordinary skill in the art to provide for the chambers of the Koop (et al) reference with ramps which assist in providing a mixing of fluids to produce droplets at the 2nd side of ramps in the form of droplets in a controlled movement of the fluids so as to produce a more effective emulsion of the mixed fluid.

Response to Arguments

9. Applicant's arguments filed 12-19-2005 have been fully considered but they are not persuasive.

10. Applicant argues with regards to the 35 USC 112, second paragraph rejection to the claims by pointing out excerpts from the specification. Although, during examination, the claims are read in the broadest interpretation in light of the specification, the text of the specification is not imported as limitations to the claims. Applicant's quotation of the specification does not point out the corresponding language in the claim(s) itself to persuade that the quoted subject matter in the specification has been directly imported into the claim.

11. Applicant alleges that the Koop reference does not show 1st and 2nd chambers connected through capillary passage ways. Applicant is referred to the rejection made above in section 5 and refer to the mark up drawing.

12. Applicant argues that the Koop reference operates in a continuous mode in contrast a batch mode as applicant discusses on page 12-13 of applicant's remarks. In response, the issues of a discrete batch mode has not been claimed in the method step nor such feature is supported in the apparatus claims such as the provision of a structural control system and valves to produce a discrete batch flow such as opening a flow into a chamber, closing the chamber from dispensing, stopping the flow of input fluids, mixing the fluids together, opening the chamber to dispense a mixed flow, and the subsequent restarting the flow of input fluids to begin the next batch. Thus such arguments presented are unpersuasive.

13. Applicant argues on pages 13-14 that the Koop has chambers substantially equal passage cross-section in all areas of passage". An alleges that the Koop's device does not correspond to applicant's invention. In response, the issue of Koop's chambers having "substantially equal passage cross-section" is not issue to the limitation of the instant claims. The claims only require a operational/structural relationship between a functional operation of the (operational) input fluid volume(s) to the physical chamber volume. With regards to the apparatus claims, as long as the structure may perform the recited operation the structure is deemed to satisfy the claimed structure. The claim is vague in scope to the input fluid volume thus it is open to interpretation to choose any smallest amount of volume which is less the combined physical volume of the chamber. In this manner, the Koop reference fully satisfies the limitations required in the claims.
14. Applicant argues with regards to the Nakajima reference, it is far different from applicant's device. In response, the Nakajima reference is applied to the Koop reference and is not applied as a modifier of applicant's device. Applicant further argues that there is no reason to combine Nakajima with the Koop reference reason and motivation is provide in the last paragraph in the rejection of section 8.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

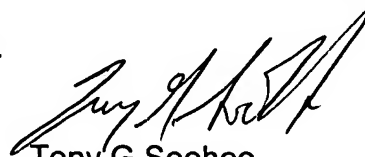
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G. Soohoo whose telephone number is (571) 272 1147. The examiner can normally be reached on 7-5PM, Tue-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tony G Soohoo
Primary Examiner
Art Unit 1723